UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

NOVO NORDISK A/S AND NOVO NORDISK INC.,

Plaintiffs,

v.

AMBLE HEALTH INC.,

Defendant.

Case No. 4:25-cv-1048

DEFENDANT AMBLE HEALTH INC.'S

MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM

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I. INTRODUCTION

We begin by envisioning Plaintiff Novo Nordisk's[1] ideal world. In this world, the law would not permit pharmacies to compound GLP-1[2] weight loss drugs at all. Novo's only competition for its FDA-approved semaglutide[3] GLP-1 drugs, Ozempic® and Wegovy®, would be the other FDA-approved GLP-1 drugs manufactured by Novo's rival, Eli Lilly's (containing tirzepatide as the active pharmaceutical ingredient. In this alternate universe, Defendant Amble Health (a telehealth platform that connects patients with doctors) could only advertise GLP-1 products manufactured by Novo or Lilly, because in Novo's ideal world, compounded GLP-1 drugs simply do not exist.

But here, in the real world, compounding drugs, including with semaglutide, is legal—explicitly authorized by Congress. And, Amble's advertisements regarding compounded drugs, including those made with semaglutide, are also legal. Novo brings this suit because Novo feels it is unfair competition for pharmacies to compound with semaglutide, as compounding reduces Novo's profits—not because Amble has engaged in any wrongdoing.

To be clear, Amble is not a compounding pharmacy—it does not compound, prescribe, manufacture, or dispense medication. Amble operates a website that connects patients with doctors for treatment—which may include prescribing drugs like GLP-1s. On Amble's website, Amble advertises GLP-1s as a possible treatment, offering to connect patients with doctors, who will ultimately use their independent medical judgment to make prescribing decisions. These doctors ***may*** prescribe compounded semaglutide; they ***may*** prescribe Novo's Ozempic® or Wegovy® semaglutide-based drugs; they ***may*** prescribe Lilly's tirzepatide-based drugs, Zepbound® or

[1] Novo Nordisk A/S and Novo Nordisk, Inc. will be referred to collectively as "Novo" or "Novo Nordisk." Throughout this brief, all emphasis is added, and citations and internal quotation marks are omitted, unless otherwise indicated.
[2] As will be described in more detail below, GLP-1 stands for "glucagon-like peptide 1 receptor agonists," a class of medications used to treat certain health conditions like diabetes and obesity.
[3] Semaglutide and tirzepatide are the active pharmaceutical ingredients used to manufacture and compound drugs within the GLP-1 drug category.

Mounjaro®; or they ***may*** prescribe nothing at all. (All of these drugs, whether semaglutide- or tirzepatide-based, and whether manufactured by Lilly or Novo, or compounded by pharmacies, fall within the broad category of "GLP-1s.")

Novo already tried suing pharmacies that compound with semaglutide, and Novo lost, repeatedly; most of its lawsuits against compounding pharmacies were dismissed outright at the pleading stage.[4] Several federal district court judges ruled that Novo cannot attack the fact that pharmacies compound with semaglutide (and thus compete with Novo and Lilly)—no private actor can step into the shoes of the U.S. Food and Drug Administration ("FDA") and enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") to police the making of compounded drugs.

Frustrated by the dismissal of its prior anti-compounding lawsuits, Novo sought another way to try and squash this supposedly-unfair compounding competition—shifting to suing platforms like Amble for ***advertising*** that pharmacies make compounded semaglutide-containing drugs to fill doctor-written prescriptions. Continuing its reality-bending efforts, in these "false advertising" and "unfair competition" lawsuits, Novo has attempted to litigate into existence a trademark on the word "semaglutide," with a corresponding prohibition for compounders (and those who advertise compounded medications) on use of the very word at all, effectively granting itself some sort of exclusive right to the chemical substance semaglutide when used as an active pharmaceutical ingredient.

Before this Court, Novo does the same, complaining that Amble advertises "personalized semaglutide." But Novo goes a step further. Unlike the other 113 cases Novo has filed in district courts across the United States where Novo challenged those defendants' statements about semaglutide, Novo's Complaint here also challenges Amble's general advertisement of "GLP-1s."

[4] *See, e.g., Novo Nordisk Inc. v. Live Well Drugstore, LLC*, No. 23-808, 2025 U.S. Dist. LEXIS 17792, *15 (M.D. Fla. Jan. 30, 2025) (dismissing Novo's claims because the federal government has "'nearly exclusive' authority to enforce the FDCA," and thus finding, Novo's federal and state law claims impliedly preempted by the FDCA).

Thus, Novo attempts to lay claim to the ***entire class of drugs*** into which Novo's drugs Ozempic® and Wegovy® fall. Novo claims telehealth platform Amble engages in false advertising by laying out various GLP-1 treatment options that independent doctors may prescribe—like "personalized GLP-1 injections" or personalized medication "tailored to you." Different, then, from its lawsuits focused on telehealth platforms' use of the word "semaglutide" (which, while those complaints are also subject to numerous legal challenges, are at least limited to the active pharmaceutical ingredient Novo itself uses in its FDA-approved drugs), Novo's instant Complaint also challenges Amble's advertisement of "GLP-1s"—a class of drugs that includes active pharmaceutical ingredients ***not used*** in Novo's own FDA-approved drugs.

From a pleading standpoint, Novo will never be able to connect Amble's GLP-1 advertisements for an entire class of drugs (which includes but is much broader than Novo's semaglutide-based drugs) to harm caused ***to Novo***. Pleading false advertising and deceptive practice act claims requires a plaintiff to state allegations that link the offending advertisement to some sort of direct harm. Here, that nexus for Novo's attacks on Amble's website's use of "GLP-1s" cannot be satisfied, because Novo does not own the GLP-1 drug category. Indeed, Novo already admitted in a different federal court that its Ozempic® and Wegovy® drugs do not serve the same market as the compounded GLP-1 drugs. Given the facts and Novo's prior admissions, Novo cannot plead a plausible link between Amble's advertisements about compounded "GLP-1s" and any reputational harm to Novo.

Stepping back even further, Novo's claims also fail because a consumer (patient) cannot decide on its own what GLP-1 medications to purchase via Amble's telehealth platform; all GLP-1s require a doctor's prescription. Via Amble's telehealth platform, doctors assess a patient, determine which medication (if any) is suitable for treatment, and then prescribe the necessary medication. Only after a doctor prescribes a GLP-1 medication can consumers (the patients)

purchase the medication (fill the prescription) from the pharmacy of their choice. Thus, the doctors' treatment determination is the actual cause of Novo's alleged inability to sell its semaglutide-based drugs; the doctor's prescription is what dictates what medication a patient acquires. The law allows dismissal of Lanham Act claims where the actions of independent actors—not the challenged advertisements—are the true cause of any alleged sales diversion.

Finally, as set out above, although Novo has been repeatedly told that it cannot use state law to enforce the FDCA, Novo is once again attempting to enforce the FDCA via Ohio's Deceptive Trade Practices Act. Novo alleges that Amble is misleading consumers as to the quality of the compounded semaglutide that independent doctors may prescribe. But, as Novo knows full well, Congress directs FDA—and FDA alone—to enforce the FDCA, which includes policing the ingredients used to make compounded semaglutide. The FDCA preempts any attempt by private parties like Novo to police drug making under the guise of various state laws.

In sum, the law prohibits a profit-motivated drug manufacturer from muzzling any mention of treatments that don't pad its own profits under the guise of false advertising and deceptive trade practices. As such, this complaint should be dismissed in its entirety.

II. FACTUAL BACKGROUND

A. GLP-1s: A General Class of Medications

Novo manufactures three FDA-approved drug products containing semaglutide as the main macromolecule and the primary active pharmaceutical ingredient ("API"): Ozempic®, Wegovy®, and Rybelsus®. Compl. ¶ 2.[5] Novo's medications belong to the general class of medications known as glucagon-like peptide 1 ("GLP-1s") receptor agonists.[6] In addition to Novo's semaglutide-based

[5] Ozempic® (injectable) is primarily used for type 2 diabetes; Wegovy® (injectable) is primarily used for weight management; and Rybelsus® (oral) is primarily used for type 2 diabetes. Compl. ¶¶ 21-25.

[6] FDA, *FDA Clarifies Policies for Compounders as National GLP-1 Supply Begins to Stabilize* (Apr. 28, 2025), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-clarifies-policies-compounders-national-glp-1-supply-begins-stabilize. This Court can take judicial notice of FDA statements. *See infra* at p. 10, **Ex. A**.

GLP-1s, Novo also manufactures a liraglutide-based GLP-1, Victoza®.[7] Novo's competitor, Eli Lilly, manufactures tirzepatide-based GLP-1s Mounjaro® and Zepbound®, and a dulaglutide-based GLP-1, Trulicity®. And, the FDA recently approved the first generic liraglutide-based GLP-1 manufactured by Hikma Pharmaceuticals USA Inc.[8]

Thus, GLP-1 is a general term, referring to an entire class of medications. Novo's semaglutide medications are not the only GLP-1s on the market. GLP-1s do not refer specifically to Novo or its medications. Novo has not trademarked the GLP-1 classification (nor could it), and Novo does not have any exclusivity over the term "GLP-1s."

B. Compounded Medications: When Doctors Determine Manufactured Drugs Are Not Appropriate for Patient Treatment

Despite Novo's characterization of compounded drugs as somehow suboptimal due to their lack of FDA-approval (Novo repeatedly uses the shorthand "Unapproved Compounded Drugs" throughout its Complaint), Congress's well-designed federal regulatory scheme intentionally exempts compounded medications from FDA's new drug approval process governing manufactured drugs (like Novo's drugs). Compounding is a legitimate, long-standing, and traditional component of pharmacy practice. It is a "process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002) ("*Western States*"). Compounding was traditionally regulated by the states, but Congress amended the FDCA to add Section 503A in 1997, giving FDA regulatory oversight over compounding. 21 U.S.C. § 353a ("Section 503A"). Section 503A did not displace state oversight but added a federal oversight layer. Compounding ensures doctors have

[7] Victoza (injectable) is primarily used for type 2 diabetes. FDA, *FDA Approves First Generic of Once-Daily GLP-1 Injection to Lower Blood Sugar in Patients with Type 2 Diabetes* (Dec. 23, 2024), *available at* https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-once-daily-glp-1-injection-lower-blood-sugar-patients-type-2-diabetes, **Ex. B**.

[8] *See id*.

access to alternative treatment options when one-size-fits-all manufactured drugs, such as Novo's, are not appropriate for patients. *Western States*, 535 U.S. at 361. Compounded medications are inherently personalized—prescribed for patients whose needs, as determined by a doctor, cannot be met by mass-manufactured drugs.

While Congress intentionally exempted compounded medications from FDA approval, Section 503A includes parameters to ensure that compounded medications remain a safe alternative, such as limiting the API that may be used to compound. *See* 21 U.S.C. § 353a(b)(1)(A)(i)(II). Section 503A specifically authorizes compounders to use API that are a "component of a drug approved" by FDA—such as the semaglutide in Novo's drugs. *Id*. Moreover, Section 503A ties compounded medications to doctor determinations that the compounded medications are necessary; a pharmacy can only compound a medication pursuant to a patient-specific prescription, or based on historical ordering patterns in anticipation of receiving a prescription for a particular patient. *See id.* § 353a(a)(2)(A)-(B). Section 503A's prescription requirement is the embodiment of "personalized," ensuring each compounded medication has been determined necessary by a doctor.[9]

C. Amble Health: A Telehealth Platform That Connects Patients to Third-Party Independent Doctors for Healthcare Services

Amble operates a website that connects patients seeking telehealth or telemedicine services with third-party, independent doctors. Amble provides technology and support services to assist patients with medical consultations and prescription logistics. These services are administrative. Amble facilitates the virtual care that third-party, independent doctors provide to patients. Amble does not engage in the practice of medicine. Amble does not provide any healthcare services. Further,

[9] FDA, *Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, 5 (Dec. 2016) ("[Section 503A's prescription requirements] are meant to help ensure that compounding … is based on individual patient needs, and that entities purportedly operating under Section 503A are not actually operating as conventional manufacturers."), *available at* https://www.fda.gov/files/drugs/published/Prescription-Requirement-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf ("FDA's Guidance Regarding the Prescription Requirement"), **Ex. C**.

Amble is not a pharmacy: it does not compound any medications, it does not dispense medications, and it does not fill prescriptions.[10]

On its webpage, Amble informs prospective patients of the third-party doctors' services, and identifies certain prescription medications that a doctor may prescribe. Among these medications, Amble informs patients that doctors may determine that GLP-1s are appropriate for treatment. Amble's advertisements do not specify between compounded GLP-1s, the FDA-approved GLP-1 medications made by Eli Lilly or Novo, or the generic liraglutide medication. Instead, Amble specifically advises patients that the prescription medications they may receive will be issued *solely* at the doctor's discretion. The independent third-party doctor may prescribe: (1) no medication; (2) an FDA-approved GLP-1, such as Ozempic® (Novo), Wegovy® (Novo), Rybelsus® (Novo), Zepbound® (Lilly), Mounjaro® (Lilly), Trulicity® (Lilly); (3) the FDA-approved generic liraglutide medication; or (4) a compounded GLP-1. Independent third-party doctors—not Amble—determine which medication, if any, is necessary for patient treatment. Following a doctor's determination, Amble can facilitate "both FDA-approved and compounded medication fulfillment via its partner pharmacy network," or a patient can decide to fill their prescription at any other pharmacy of their choosing. *Id.*

III. NOVO'S COMPLAINT: A CONTINUATION IN NOVO'S LONG EFFORT TO STOMP OUT COMPOUNDED MEDICATIONS AND REDUCE COMPETITION

In 2023, Novo started its nation-wide anticompetitive campaign against compounded semaglutide medications. Novo's efforts began in Florida, filing federal court lawsuits attacking compounding as violating Florida state law. Those lawsuits failed because courts refused to allow Novo to use state law as a vehicle to enforce the FDCA. The FDCA contains no private right of action; only FDA is entitled to bring actions to enforce or restrain alleged violations of the FDCA. 21 U.S.C. § 337(a) (instructing that "all such proceedings for the enforcement, or to restrain

[10] *See* "Important Safety Information," Amble Health's website, attached as **Ex. D**.

violations, of [the FDCA] shall be brought by an in the name of the United States.").[11]

Since then, Novo shifted to attacking ***advertising*** around compounded medicines, whether by those who compound using semaglutide, or those who advertise services around semaglutide-containing medicines. But here, Novo goes further, purporting to lay claim to the ***entire*** GLP-1 class of drugs, complaining that Amble is doing something wrong by describing GLP-1s as "personalized." Compl. ¶ 46. The factual allegations supporting Novo's personalization theory follow:

- "Defendant runs sponsored advertisements for "Personalized Semaglutide." Compl. ¶ 47.
- "On its website, Defendant claims to offer "Personalized GLP-1 Injections." Compl. ¶ 48.
- "Defendant advertises on its website, 'Prescription medication, *tailored to you.*'" Compl. ¶ 49 (emphasis in original).
- "On its website, Defendant answers the question 'Why Amble' by stating that Amble provides 'prescription medications tailored to your personal goals.'" Compl. ¶ 50.
- "[O]n its website, Defendant further describes its Unapproved Compounded Drugs with the statement: 'Compounding involves the personalization of active ingredients, dosages, and form of medication to meet an individual's personal needs. Compounded medications are prescribed by licensed healthcare providers and made in licensed pharmacies. Personalized GLP-1 products are available as compounded injectable and have not received FDA approval.'" Compl. ¶ 51.

According to Novo, these statements are false and misleading because "upon information and belief, the compounded semaglutide drugs that Defendant offers and claims are not 'personalized' are ordered in bulk from one or more compounding pharmacies and then mass re-

[11] *Novo Nordisk Inc. v. Brooksville Pharms. Inc.*, No. 23-cv-1503, 2023 WL 738519, *3-4 (M.D. Fla. Nov. 8, 2023) (Novo's claims under Florida's Deceptive and Unfair Trade Practices Act fail because "[the FDCA] is a critical element of a [state claim]" and "the [c]ourt can identify no alleged conduct that would give rise to liability under state law even if the [FDCA] did not exist"); *Novo Nordisk Inc. v. WellHealth Inc.*, 764 F. Supp. 3d 1193, 1202 (M.D. Fla. Jan. 30, 2025) (holding that Novo Nordisk's claim is preempted by the FDCA because "the existence of the FDCA is a critical element"); *Novo Nordisk Inc. v. Live Well Drugstore, LLC*, No. 23-808, 2025 U.S. Dist. LEXIS 17792, *15 (M.D. Fla. Jan. 30, 2025) (finding Novo Nordisk's claims preempted as an attempt to unlawfully bring a private action to enforce FDCA compliance, which solely rests within FDA's authority); *see also Novo Nordisk Inc. v. Wells Pharmacy Network, LLC*, No. 23-00689, 2025 U.S. Dist. LEXIS 25356, *18 (M.D. Fla. Feb. 12, 2025) (noting that while Wells Pharmacy did not seek dismissal on preemption grounds, "similar [Florida Deceptive and Unfair Trade Practices Act] lawsuits have been dismissed on preemption grounds, and preemption would likely apply here").

sold to patients on a cookie-cutter basis." Compl. ¶ 52. Further, Novo claims that the "tailored" to patient needs statement is false because allegedly "a consultation with a doctor is not required or offered before Defendant prescribes its compounded semaglutide medications." Compl. ¶¶ 53-54. And, because "defendant [] does not personalize for specific patient its compounded semaglutide drugs through its offered dosages" rather patients are prescribed "a standardized dosage plan for its unapproved drugs." Compl. ¶¶ 60-61. Collectively, Amble refers to these allegations as Novo's "Personalization Theory."

Although Novo's causes of actions relate to complaints about Amble's "personalized" advertisements, Novo's request for relief seeks an order from the Court enjoining and restraining Amble from making all sorts of statements, the vast majority of which are not alleged in the Complaint:

(a) "advertising, stating, or suggesting that any Unapproved Compounded Drugs . . . :

i. are or contain genuine or authentic Novo Nordisk Ozempic®, Wegovy®, or Rybelsus® medicines;
ii. are sponsored by or associated with Novo Nordisk;
iii. are approved by the FDA; have been reviewed by the FDA for safety, effectiveness, or quality; or have been demonstrated to the FDA to be safe or effective for their intended use;
iv. achieve or have been shown or proven to achieve therapeutic results, effects, outcomes, including but not limited to by relying on or making reference to clinical trial results for Novo Nordisk's medicines;
v. achieve or have been shown or proven to achieve therapeutic results, effects, or outcomes similar or identical to Novo's medicines or are interchangeable with or equivalent to genuine Novo Nordisk medicines;
vi. are associated or connected in any way with Novo Nordisk or Novo Nordisk's medicines; or
vii. contain any ingredient (including semaglutide) that is supplied by Novo Nordisk, is approved by the FDA, or is the same as any ingredient in Novo Nordisk medicine;
viii. are personalized, customized, or otherwise tailored to individual patients.

Compl., Request for Relief ¶ 3.

IV. LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (*quoting Bell Atlantic v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial

plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The court must determine whether the factual allegations in a complaint state a plausible claim for relief based on "judicial experience and common sense." *Id.* at 679.

When ruling on a Rule 12(b)(6) motion, a court may consider the "Complaint, and any exhibits thereto, public records, items appearing in the record of the case and exhibits attached to defendant's motion to dismiss so long as they are referred to in the Complaint and are central to the claims contained therein." *Bassett v. NCAA*, 528 F.3d 426, 430 (6th Cir. 2008). A court may, in undertaking a 12(b)(6) analysis, take judicial notice of "matters of public record, orders, items appearing in the record of the case, and exhibits attached to the complaint." *Elec. Merch. Sys. LLC v. Gaal*, 58 F.4th 877, 883 (6th Cir. 2023); *In re Sotera Health Co. Sec. Regul.*, No. 23-143, 2025 U.S. Dist. LEXIS 49837, *60-61 (N.D. Ohio. Mar. 19, 2025) (in ruling on a motion to dismiss, courts can consider documents attached to or referenced in a plaintiff's complaint, public records subject to judicial notice, or extrinsic documents central to plaintiff's claims). Sixth Circuit courts frequently "take judicial notice of federal regulatory agency materials." *Fox v. Kia Am., Inc.*, 726 F. Supp. 3d 765, 774 (N.D. Ohio 2024). Here, the court can consider Amble's statements (whether attached to plaintiff's complaint or this motion), as well as FDA materials as matters of public record, in evaluating this motion to dismiss.

V. ARGUMENT

A. Plaintiff's False and Misleading Advertising Claims Fail

Novo has brought two claims for false advertising—one under the Lanham Act and one under the Ohio Deceptive Trade Practices Act ("ODTPA"). The analysis for false advertising under the ODTPA is the same as the Lanham Act. *Stilson & Assocs., Inc. v. Stilson Consulting Grp., LLC*, 129 F. App'x 993, 994 (6th Cir. 2005) ("The standard applicable to Lanham Act claims governs

Plaintiffs' ... claims under the Ohio Deceptive Trade Practices Act ….”); *HER, Inc. v. RE/MAX First Choice, LLC.*, 468 F. Supp. 2d 964, 979 (S.D. Ohio 2007) (“‘[A]n analysis appropriate for a determination of liability under . . . the Lanham Act is also appropriate for determining liability under the Ohio Deceptive Trade Practices Act.’”). Therefore, Amble treats Novo's ODTPA and the Lanham Act claims together in this motion.

To prove a claim for false advertising or commercial disparagement under the Lanham Act § 1125(a)(1)(B) (Novo's Count I), a plaintiff must establish that: (1) the defendant has made false or misleading statements of fact concerning his product or another's; (2) the statement actually or tends to deceive a substantial portion of the intended audience; (3) the statement is material in that it will likely influence the deceived consumer's purchasing decisions; (4) the advertisements were introduced into interstate commerce; and (5) there is some causal link between the challenged statements and harm to the plaintiff. *Herman Miller, Inc. v. Palazzetti Imps. & Exps., Inc.*, 270 F.3d 298, 323 (6th Cir. 2001); *see also Reed Elsevier, Inc. v. TheLaw.net Corp.*, 269 F.Supp.2d 942, 951 (S.D. Ohio 2003) (citing same elements for ODTPA, Novo's Count II).

Novo has failed to properly plead the first, second, third, and fifth elements. Amble begins with the fifth element regarding Novo's lack of harm, because, even beyond its pleading failures, Novo fundamentally has no basis to allege harm from any of Amble's advertising—and has failed to plausibly do so in the Complaint. Novo cannot establish a viable connection between Amble's use of general terms such as “personalized “medication,” “personalized GLP-1s,” and “personalized semaglutide” and any alleged harm suffered by Novo.

1. Novo Fails to Allege How Advertisements for “Personalized Medication,” “Personalized GLP-1s,” or “Personalized Semaglutide” Cause Novo Harm.

To survive a motion to dismiss, Novo must allege some non-speculative commercial injury to its reputation or sales. *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 132-

133 (2014). The Lanham Act's purpose is "to protect parties only against 'injuries to business reputation and present and future sales.'" *Lewis v. Acuity Real Est. Servs., LLC*, 63 F.4th 1114, 1118 (6th Cir.2023) (quoting *Lexmark*, 572 U.S. at 131). Recovery under the Lanham Act "is limited to plaintiffs whose injuries are ***proximately*** caused by violations of the statute.'" *Uriah Prods., LLC v. Winston Prods., LLC*, No. 24-1493, 2025 U.S. Dist. LEXIS 104751, *11 (N.D. Ohio June 3, 2025) (quoting *Lexmark*, 572 U.S. at 132); *cf. Hemi Group, LLC v. City of New York*, 559 U.S. 1, 9 (2010) ("Proximate cause thus requires some direct relation between the injury asserted and the injurious conduct alleged. A link that is too remote, purely contingent, or indirect is insufficient.") (cleaned up).

There must, therefore, be facts pleaded that demonstrate the plaintiff has suffered "economic or reputational injury flowing directly from the deception wrought by the defendant's advertising," which occurs "when deception of consumers causes them to withhold trade from the plaintiff." *Lexmark*, 572 U.S. at 133. In other words, to support a Lanham Act claim, plaintiff must plead "some causal link between the challenged statements and harm to the plaintiff." *Grubbs v. Sheakley Grp.*, 807 F.3d 785, 798 (6th Cir. 2015)). A failure to adequately plead the fifth element, as Novo has here, is dispositive. *See Uriah Prods.*, 2025 U.S. Dist. LEXIS 104751, *10-13 (dismissing plaintiff's Lanham Act claims because plaintiff could not plead facts to demonstrate that they suffered harm arising out of the defendant's alleged violation of the Act).

a. Novo Cannot Plausibly Plead Reputational Harm Based on Amble's "Personalization" or "Tailoring" Advertisements

Novo cannot establish a plausible connection between Amble's purported violations of the Lanham Act and Novo's purported reputational harm; therefore, Novo's claims must fail. *Grubbs*, 807 F.3d at 798. Novo alleges that Amble's "personalized medications," "personalized GLP-1s," and "personalized semaglutide" statements will expose patients to "unnecessary risks." Compl. ¶

68. According to Novo, patients who "mistakenly believe Defendant to be individually personalized medicines are unlikely to understand the risks associated with, Defendant's Unapproved Compounded Drugs"; and "this conduct threatens to undermine the reputation for quality and safety established on Novo Nordisk's FDA-approved medicines." *Id.*

But, Novo fails to allege any factual support for how general references to "personalized medications," "personalized GLP-1s," and "personalized semaglutide" would lead to the implausible result that Novo's reputation would be damaged—when none of those terms are specific to Novo. *Int'l IP Holdings, LLC v. Vitamin Energy, Inc.*, No. 19-11716, 2023 U.S. Dist. LEXIS 179147, *16-17 (E.D. Mich. Oct. 4, 2023) (dismissing counterclaims because there were "no facts connecting Plaintiffs' false advertising's influence on consumers and any economic reputational harm suffered by Defendant"). Novo simply cannot establish reputational harm based on Amble's general statements—statements that provide no connection at all to Novo or Novo's medications. Under Novo's multi-step theory, a patient would need to (1) see an advertisement from Amble for "personalized GLP-1s," "personalized medications," or "personalized semaglutide," (2) join into Amble's program, (3) have a doctor determine that compounded GLP-1s are appropriate for their treatment, (4) have a negative experience with compounded GLP-1s, (5) believe that it was deceived by Amble as to the safety of compounded GLP-1s (ignoring Amble's numerous notifications informing patients of the lack of FDA-approval and FDA-review of safety and efficacy), and then (6) take this negative reaction out on Novo because Novo makes and sells Ozempic® and Wegovy®. Novo has pleaded absolutely none of these facts and absolutely no facts to support any inference that this speculative harm could occur. *NetJets Aviation, Inc. v. Perlman*, No. 22-2417, 2024 U.S. Dist. LEXIS 173552, *11 (S.D. Ohio Sep. 25, 2024) (dismissing false advertising claim where no facts supported an inference of harm).

Moreover, Novo fails to address the context for these advertisements, and that context

further demonstrates the implausibility of Novo's conclusory reputational harm allegations. *See Wysong Corp. v. APN, Inc.*, 889 F.3d 267, 270 (6th Cir. 2018) (explaining that the context of the advertisement matters when evaluating plausibility). Novo does not explain how patients would make the leap from a negative experience with any compounded GLP-1 to holding Novo responsible for this negative experience—Novo's name is not on the compounded GLP-1, nor is Novo or its medications mentioned anywhere in Amble's advertisements. Similarly, Novo does not explain how patients will misunderstand the risks associated with compounded GLP-1s when Amble repeatedly and continually informs patients of the risks. *See* Amble Patient Safety Information, **Ex. D**. Amble advises patients that compounded medications are not FDA-approved and are not FDA-reviewed for safety or efficacy. *Id*. And Novo does not plead any facts to plausibly suggest that a patient who somehow does misunderstand these numerous warnings about compounded GLP-1s will somehow blame Novo. Novo has entirely failed to set forth any facts establishing a plausible basis for any reputational harm.

Further, Novo knows full well it already admitted that the term "GLP-1" is not specific to its drugs—highlighting the absence of any plausible connection between Amble's statements and Novo's purported reputational harm. By way of background, in 2022, FDA declared that Novo's semaglutide-based drugs Ozempic® and Wegovy® were "in shortage." The effect of FDA's shortage declaration meant that during Novo's drug shortage, like in any drug shortage, compounders were statutorily-authorized to make exact copies of Novo's drugs in order to meet patient need.[12] Two years later, in December 2024, FDA determined Novo could meet patient need,

[12] *See* FDA, *Guidance for Industry: Compounded Drugs that Are Essentially Copies of a Commercially Available Drug Product Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, p. 5 (Jan. 2018) (authorizing compounding of drug products that are on FDA's Drug Shortage List because they are not commercially available), *available at* https://www.fda.gov/files/drugs/published/Compounded-Drug-Products-That-Are-Essentially-Copies-of-a-Commercially-Available-Drug-Product-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf ("FDA's Essential Copies Guidance"), **Ex. E**.

and thus declared the shortage resolved.[13]

FDA's decision to declare the shortage over was challenged in federal court, and Novo intervened to support FDA's determination that Novo could meet patient need for its semaglutide-based drugs. In its briefs, Novo addressed the key issue of whether it could adequately meet patient need for semaglutide-based medications, including patients being treated with compounded GLP-1s.[14] Novo explained that including the patients being treated with compounded GLP-1s was "***not*** an appropriate estimate to project demand" for Novo's approved Ozempic® and Wegovy®, confessing that "compounded GLP[1]s should ***not*** be understood to represent a 1:1 future demand for Novo Nordisk's semaglutide injection products." Novo's Texas Opp. Br. at 3. According to Novo, "that estimate includes compounding of *other* GLP-1 products (e.g., tirzepatide products)." *Id*. In affirming FDA's determination, the Court relied on Novo's explanation that compounded GLP-1s included the "compounding of both tirzepatide and semaglutide, so *it included drugs not at issue here*." *Outsourcing Facilities Ass'n v. United States FDA*, No. 25-00174, 2025 U.S. Dist. LEXIS 115102, *7-8 (N.D. Texas June 13, 2025). Thus, Novo and the Court agreed that GLP-1s is a broad category of drugs that includes more than just Novo's drugs.

Now, in contrast to its prior position taken in that recent federal court case, Novo asks this Court to believe that GLP-1s and Novo's drugs ***are one and the same***. And, that Novo is directly harmed when Amble generally advertises "personalized GLP-1s," claiming that patients will tie this term to Novo and its reputation. Novo cannot have it both ways—the Court should reject any arguments from Novo that it could be harmed from advertisements referring to the general class

[13] Following the shortage's resolution, compounders may continue to compound using semaglutide API in accordance with Section 503A and FDA guidance. 21 U.S.C. § 353a(b)(1)(D); FDA Essential Copies Guidance, **Ex. E** *supra* note 12, at 5-6.

[14] Intervenor-Def.'s Br. in Opp. to Pl.'s Mot. for Summ. J., *Outsourcing Facility Ass'n v. United States FDA*, No. 25-0174 (N.D. Tex. June 12, 2025) (ECF No. 87) ("Novo's Texas Opp. Br.").

of medications, GLP-1s.[15] Because Amble's advertisements are completely unrelated to Novo and its medications, Novo cannot establish a proximate connection between the advertisements at issue and Novo's purported reputational harm. Therefore, Novo's claims should be dismissed.

b. Novo Cannot Plead Plausible Harm Because Intervening Third-Party Doctors—Not Amble—Determine Whether Compounded GLP-1s or Novo's Manufactured GLP-1s Should Be Prescribed

Novo cannot link Amble's purported unlawful activity under the Lanham Act to any purported patient diversion harming Novo. Novo conclusorily alleges that Amble's "personalized medication," "personalized GLP-1s," and "personalized semaglutide" statements will "divert consumers from Novo Nordisk's FDA-approved medicines with the false promise that Defendant's drugs are personalized to the patient's individual needs." Compl. ¶ 67. But independent, third-party doctors—not Amble—determine whether a patient receives a compounded GLP-1 or Novo's Ozempic® or Wegovy®. 21 U.S.C. § 353a(a) (requiring that a compounded medication be tied to a "prescription order that a compounded product is necessary for the identified patient."). These determinations are based on the doctor's independent clinical judgment—not Amble's advertisements. Therefore, it is impossible to connect any compounded GLP-1 prescribing to Amble's "personalized" statements with which Novo takes issue.

The fatal impact of Novo's inability to plead patient diversion is underscored by the district court's and Sixth Circuit's reasoning in *Geomatrix*. *Geomatrix, LLC v. NSF Int'l*, 629 F. Supp. 3d 691, 709 (E.D. Mich. Sept. 21, 2022), *aff'd* 82 F.4th 466 (6th Cir. 2023). Plaintiff alleged defendants made false statements about the effectiveness and environmental impact of plaintiff's

[15] *Borror Prop. Mgmt., LLC v. Oro Karric N., LLC*, 979 F.3d 491, 495 (6th Cir. 2020) (statements in pleadings, admissions during discovery, and arguments to court by counsel are binding judicial admissions when made deliberately, clearly, and unambiguously); *Eubanks v. CBSK Fin. Grp., Inc.*, 385 F.3d 894, 897 (6th Cir. 2004) ("[J]udicial estoppel bars a party from asserting a position that is contrary to one the party has asserted under oath in a prior proceeding."); *MacDonald v. Gen. Motors Corp.*, 110 F.3d 337, 340 (6th Cir. 1997) (attorney statements can be binding judicial admissions); *Williams v. Union Carbide Corp.*, 790 F.2d 552, 555-56 (6th Cir. 1986) (finding that statements made in other lawsuits, including statements of a party's attorney, may be evidentiary admissions).

products, which allegedly resulted in certain state environmental regulators denying plaintiff the right to sell its products in those states. *Id*. The district court found that the ***actual*** cause of plaintiff's harm was the "independent decision of each state's environmental regulators not to approve the [plaintiff's] products for sale." *Id*. The court reasoned that the "state regulators could have independently concluded that Plaintiff's GeoMat product poses environmental risks, the bureaucracy could simply be even 'slow[er] to allow new technologies' than Plaintiff anticipated, or it could be a combination of factors." *Id*. at 710. Thus, because there was an "extenuated causal chain" with "other, independent, factors" intervening, Plaintiff could not provide a viable proximate causation theory linking defendant's purported unlawful activity to an alleged injury, and its claims were dismissed. *Id*.

The Sixth Circuit affirmed, agreeing that the independent state regulators' decisions to deny approval of plaintiff's products were the "intervening cause and the proximate one" of plaintiff's harm. 82 F.4th at 484. Going one step further than the district court, the Sixth Circuit found that plaintiff could not establish that "any deceptions on defendants' part was [] the cause of consumers' decisions, for consumers were not the ones that decided to do anything." *Id*. As such, plaintiff could not satisfy *Lexmark*'s proximate cause analysis. *Id*.

Novo's proximate cause theory fails for the same reason. Intervening and independent factors present break any purported connection between Amble's advertisements and alleged patient diversion from Novo (*i.e.*, withheld sales). Accepting Novo's "diversion theory" would require this Court to erase the doctor's role in the care and treatment of patients, and the independent clinical determinations doctors make when selecting the appropriate medication. *See generally* Ohio Medical Practice Act, O.R.C. § 4731.01 *et seq*. Doctors rely upon a myriad of factors when selecting the appropriate medications to treat their patients such as the patients' medical history, the patients' comorbidities, and the patients' treatment goals, as well as the

approved uses for commercially available medications.

Novo pleads absolutely no factual allegations explaining how a doctor's independent judgment is even theoretically co-opted by Amble's "personalized" medications advertisements. Instead, Novo (by its utter silence with respect to the obvious existence of the doctor in prescribing) implicitly asks the Court to ignore the doctor altogether and pretend that independent clinical judgment does not drive medication determinations. This Court is not required to accept entirely implausible implied factual assertions. *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 570 (courts may reject as implausible allegations that are too speculative to warrant further factual development).

Moreover, Novo's proximate cause theory falsely assumes that doctors are always choosing between Novo's GLP-1s and compounded GLP-1s. But there are a number of GLP-1s on the market—a doctor *may* decide to prescribe a compounded GLP-1, *or* a commercially available GLP-1, *or* a GLP-1 containing semaglutide (such as Novo's drugs), *or* a GLP-1 containing tirzepatide (such as Eli Lilly's drugs), *or* a GLP-1 containing liraglutide (such as the generic version of Victoza®)—*or* nothing. Doctors consider endless variables when making treatment decisions, and Novo has failed to plead any facts showing Amble's advertisements impact any of those determinations.

Novo's prior admissions before the Texas federal district court —that compounded GP1-s are not prescribed for the same patient population as Novo's drugs—also bind Novo here (*Williams*, 790 F.2d at 555-56) and are fatal to its "patient diversion" claim. Novo admitted that "compounded GLP[1]s should *not* be understood to represent a 1:1 future demand for Novo Nordisk's semaglutide injection products," because patients being treated with compounded GLP-1s "include[] *uses* that are *inconsistent* with the approved labeling for Ozempic and Wegovy." *See* Novo's Texas Opp. Br., *supra* note 17, at 3. Novo asserted "a substantial portion" of patients allegedly receiving compounded medications were

being prescribed for "uses like purely cosmetic or aesthetic weight loss." In agreeing with FDA, the Court relied on Novo, finding that demand for compounded GLP-1s did not represent demand for Novo's drugs because compounded GLP-1 patients include "unapproved or off-label users" that would not be appropriate for treatment with Novo's drugs. *Outsourcing Facilities Ass'n*, No. 25-174, 2025 U.S. Dist. LEXIS 115102, *8 (N.D. Tex. June 13, 2025). Therefore, Novo cannot claim that Amble's advertisements divert patients from Ozempic® and Wegovy®—even Novo acknowledges that doctors, relying on their independent judgment, do not prescribe Novo's drugs to the same patient population being treated with compounded GLP-1s.

Independent doctors are the "intervening cause and the proximate one" of any compounded GLP-1s prescribing. *Geomatrix*, 82 F.4th at 484. Because Novo cannot plausibly allege Amble's advertisements were a proximate cause of any purported patient diversion, its claims should be dismissed.

c. Novo Failed to Plead Sufficient Facts to Show a Causal Link Between Amble's Advertisements and Novo's Harm

Even if Amble's advertisements were the type from which Novo could be harmed, it has failed to plead sufficient facts to show such harm. Just last month, in *Uriah Products*, the Court dismissed a Lanham Act claim where the plaintiff failed to "actually allege any reputational damage or injury." 2025 U.S. Dist. LEXIS 104751, *12. Uriah sued Winston for patent infringement; Winston counterclaimed for deceptive trade practices under the Lanham Act and ODTPA. Winston's counterclaim was based on Uriah sending a letter to one of Winston's customers (Autozone) saying that Winston was infringing one of Uriah's patents. Winston averred that the allegations in Uriah's letter were false, and by sending that letter to its customer, Uriah "'obviously' damaged [Winston's] reputation." *Id*. The Court disagreed, finding it was not enough for Winston to "conclusorily allege[]" harm to its reputation without factual support." *Id*. The Court noted that there was no allegation or support to show that the letter influenced the purchasing

decisions of the customer (Autozone), that Winston lost sales, or that that Autozone took any action in response to the letter. *Id*. Thus, Winston failed to connect the alleged violation of the Act (false statements in the letter) to its purported harm (lost sales).

Uriah notes that when faced with similar pleading failures, numerous other "courts have dismissed Lanham Act claims for failure to state a claim." *Id*. *13 (citing *Geomatrix LLC*, 82 F.4th at 483-84 (affirming dismissal of Lanham Act false advertising claim under Rule 12(b)(6) where plaintiff's complaint alleged that defendants' disparagement caused "independent harm in the market and influenc[ed] consumers' purchasing decisions," but the complaint failed to describe what "independent harm" occurred in the market or how defendants' actions actually "influenc[ed] consumers' purchasing decisions"); *Plateau Casualty Ins. Co. v. Securranty, Inc*., 608 F. Supp. 3d 566, 571 (M.D. Tenn. 2022) (dismissing Lanham Act claim under Rule 12(b)(6) for failure to sufficiently allege causation of harm); *Int'l IP Holdings, LLC*, 2023 U.S. Dist. LEXIS 179147, *17 (dismissing where "Vitamin Energy's Counterclaim does not contain factual allegations sufficient to establish a causal link between Innovation Ventures' alleged false advertisements and harm to Vitamin Energy."); *see also NetJets Aviation, Inc.*, 2024 U.S. Dist. LEXIS 173552, *11 (dismissing false advertising claim where the Court found there could be no injury to reputation or sales for new business because plaintiff "has not made factual allegations which support an inference that he is competing with NetJets and has suffered an injury to his business reputation or sales.").

Here, Novo has failed to plead sufficient facts to support an allegation of harm to its reputation or that it could lose sales because of Amble's advertisements. Instead, Novo makes conclusory and speculative allegations that Amble's advertisements "divert[] consumers" from Novo to Amble (Compl. ¶ 67) and that Amble's platform exposes patients to risks because a doctor could prescribe a compounded medication that could "undermine the reputation for quality and

safety established on Novo." *Id*. ¶ 68. Novo elsewhere parrots threadbare recitations of the harm elements. *See id*. ¶¶ 75-77, 84. But Novo must plead facts to show how sales have been or could be lost by Amble's advertisements, or allege facts showing how Amble's advertisements—the text of which have absolutely nothing to do with Novo—have or could harm Novo's reputation. Because Novo entirely failed to do so, its claims must be dismissed.

2. Novo Failed to Plead Facts Establishing That Amble's Advertisements for "Personalized" Compounded Medicine Are False or Misleading.

The Lanham Act distinguishes between literally false ads and those which, while true, are misleading in context. *Wysong*, 889 F.3d at 270. False statements are those that convey "an unambiguously deceptive" meaning and are "presumed to have deceived its intended audience." *FedEx Ground Pkg. Sys., Inc. v. Route Consultant, Inc.*, 97 F.4th 444, 453 (6th Cir. 2024) (quoting *Wysong*, 889 F.3d at 270). Absent literal falsity, plaintiff must show that a "significant portion of reasonable consumers were *actually* deceived by the defendant's messaging." *Wysong*, 889 F.3d at 271. To meet this burden, at the motion to dismiss stage, the complaint must contain facts to "support a plausible inference that the challenged advertisements in fact misled a significant number of reasonable consumers." *Id*. The facts must explain "why and how" the statement is misleading. *FedEx*, 97 F.4th at 454. Context matters to the Court's evaluation of whether a reasonable consumer would be misled. *See Wysong*, 889 F.3d at 272 (finding that the plaintiff's claims were not plausible when evaluating the claims in the context of the relevant market and the products' labeling).

The Lanham Act also only provides relief for false or misleading representations of ***fact***. Statements of opinion or "puffery" are not actionable. *See Interactive Prods. Corp. v. a2zz Mobile Office Sols.*, 326 F.3d 687, 699-700 (6th Cir. 2003) (holding that a statement that is "mere puffery" is "not actionable under the Lanham Act."). "If the statement asserts a 'specific and measurable claim, capable of being proven false or of being reasonably interpreted as a statement of objective fact,' and it can be proved through 'empirical verification,' then it qualifies as a statement of fact." *Mircostar Logistics LLC v. Cavalier Dist. Co.*, No. 24-647, 2025 U.S. Dist. LEXIS 46968, *7 (S.D. Ohio Mar. 14, 2025) (quoting *FedEx*, 97 F.4th at 453). When a statement constitutes non-actionable puffery, the Court may dismiss the claim at the 12(b)(6) stage. *See Wysong*, 889 F.3d at 271.

Novo has failed to plead any facts to support the first and second elements of a Lanham Act claim because Amble's advertisements are not false, Novo has failed to plead facts demonstrating reasonable consumers were misled or could be misled by the advertisements, and the statements with which Novo takes issue are mere puffery and do not provide a basis for liability under the Act.

a. Amble's Advertisements Are Not Literally False

Novo cannot plead any facts to demonstrate literal falsity because there is nothing "unambiguously deceptive" about Amble's use of the word "personalized" in its advertisements. *Wysong*, 889 F.3d at 271 ("[O]nly an 'unambiguously' deceptive message can be literally false."). Novo claims that Amble referring to its services and compounded medications as "personalized" is false because the medications are "ordered in bulk from one or more compounding pharmacies." Compl. ¶ 52. And, "upon information and belief," "a consultation with a doctor is not required or offered before Defendant prescribes its compounded semaglutide drugs," with patients being "'approved' for the unapproved compounded semaglutide drugs in a matter of days." *Id.* ¶¶ 54-55. Further, Amble allegedly "does not personalize for specific patients its compounded semaglutide drugs through its offered dosages." *Id.* ¶¶ 60-62.

But, Amble's use of the term "personalized" is not unambiguously deceptive. Rather, as used by Amble in its advertising, "personalized medications," "personalized GLP-1s," and "personalized semaglutide" are all true representation that the medications are prescribed based on the personal attributes of the individual patient. Amble advises patients of this fact by advising that "a licensed medical provider will review your medical history" and determine for each patient what medication is appropriate for that individual's "specific needs." Compl., Ex. B.

Under Amble's reasonable reading of the word, a doctor analyzes a patient's "personalized" medical history, lifestyle information, and goals, and then decides whether to prescribe medication

"if the medication is right for you and your specific needs." Compl., Ex. B. Thus, Amble's use of "personalized" cannot be literally false because it conveys a truthful message—even if that message is a different one that Novo would like. *FedEx*, 97 F.4th at 453 ("[A] statement is not literally false if it reasonably conveys different messages.").

Moreover, Novo advances an unduly narrow view of the term "personalized" to mean that each medication received by a patient must be different in order for the medication to be "personalized." *See* Compl. ¶ 53 (alleging that medication is not "personalized" because it is not "specifically compounded for particular patients"). For example, doctors regularly can and do prescribe the same medication for patients that have similar needs. Treatment plans for ear infections do not fail to be "personalized" because multiple patients are prescribed the same antibiotic. Here too, a patient's needs are examined and diagnosed by a doctor who determines the best plan for a patient, personally. Surely, "a reasonable consumer could understand" that "personalization" is tied to a ***doctor's*** determination of what medications are necessary to treat their medical needs. *See Wysong*, 889 F.3d at 271 (affirming a motion to dismiss because the photographs of premium cuts of meats could not be considered "literally false" because a "reasonable consumer could understand" that the photographs did not depict the actual cuts of meats used in low-cost dog food). Thus, there is nothing false about Amble's statements of "personalized" care and medications.

Further, compounded medications by their very nature are "personalized" medications. Doctors prescribe compounded medications when they determine that mass-manufactured medications, such as Novo's Ozempic® and Wegovy®, are unsuitable for the specific patient's treatment. *Western States*, 535 U.S. 357, 360-61 (defining compounding as the "process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication ***tailored*** to the needs of an individual patient"). Section 503A sets forth the parameters for how compounded

medications are "personalized" or "tailored to the needs of an individual patient." *See* 21 U.S.C. § 353a(a) (requiring the issuance of a prescription order showing that "a compounded product is necessary for the identified patient"). And, therefore, drugs compounded under Section 503A are *per se* "personalized" under the regulatory scheme. *FedEx*, 97 F.4th at 453.

Novo pleads, "upon information and belief," that compounded medications that may be prescribed through Amble's telehealth platform are not "personalized" because they are not specifically compounded for "particular patients or 'tailored' to patient needs." Compl. ¶ 53. But Section 503A does not require that a compounder make medications one-by-one tailored to a particular patient. Section 503A ***explicitly*** authorizes compounders to assess patient needs and create batches of compounded medications for subsequent dispensing pursuant to a prescription issued for a specific patient after a doctor has determined the compounded medication is necessary for treatment. *See* 21 U.S.C. § 353a(a)(2)(A)–(B)(i)(ii)(I)-(II) (allowing medications to be compounded based on historical orders as long as the medications are dispensed pursuant to a prescription issued for a specific patient). Under Section 503A, the doctor's issuance of the prescription for a compounded medication after determining this compounded medication is necessary for the particular patient is what makes the compounded medication "personalized."[16] Thus, Amble's statements regarding "personalization" are literally true as determined by Section 503A and FDA. Yet, Novo asks this Court to "directly conflict[] with [FDA]'s policy choice" and otherwise "undermin[e] [FDA's] judgment," which is precluded. *Pom Wonderful, LLC v. Coca-Cola Co.*, 573 U.S. 102, 120 (2014); *Allergan U.S. v. Imprimis Pharms., Inc.*, No. 17-1551, 2017 U.S. Dist. LEXIS 223117, *19 (C.D. Cal. Nov. 14, 2017) (even after *Pom Wonderful*, "some claims *some* claims *may* require the expertise of the FDA to resolve; "claims where the law is

[16] *See* FDA's Guidance Regarding the Prescription Requirement, **Ex. C**, *supra* note 9 ("[Section 503A's prescription requirements] are meant to help ensure that compounding … is based on individual patient needs ….").

unclear and the FDA's particular expertise or rulemaking authority is required are precluded by the FDCA") (quoting *JHP Pharms., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 999 (C.D. Cal. 2014)) (emphasis in original). In the absence of a false statement of fact, Novo's "Personalization Theory" cannot survive a motion to dismiss.

Because there is nothing "unambiguously deceptive" about the word "personalized" used in any context on Amble's advertisements or in the Complaint, Novo's allegations cannot survive a motion to dismiss. *FedEx*, 97 F.4th at 453.

b. Novo Fails to Allege that Amble's Advertisements Actually or Tends to Deceive a Substantial Portion of the Intended Audience

Because Novo cannot show that any of Amble's statements are literally false, to plausibly state a claim, Novo must sufficiently allege that Amble's advertisements are nonetheless misleading and deceive consumers. *See Wysong*, 889 F.3d at 271 ("At motion-to-dismiss stage, in the absence of such surveys, we ask whether the facts in the complaint support a plausible inference that the challenged advertisements in fact misled a significant number of reasonable consumers."). This assessment is guided by "judicial experience and common sense." *Id.*

The Sixth Circuit Court's analysis in *Wysong* is instructive on this point. 889 F.3d 267. In *Wysong*, plaintiff sued defendants under the Act based on premium meat cuts displayed on dog food packaging because defendants' food allegedly used lower quality cuts. *Id.* at 271. Affirming dismissal of plaintiff's complaint, the Sixth Circuit held plaintiff's misleading and deceptive theory left too many questions unanswered—such as what consumer expectations were for dog food products, whether defendants' lesser priced products competed with plaintiff's premium quality products, and whether there were obvious ways that consumers could distinguish between defendants' products and fancier brands (like plaintiff's). Plaintiff's misleading theory further failed to explain why defendants' packages' ingredient lists—identifying the specific meat cuts

used in the dog food—did not dispel the photographs' allegedly misleading effects. *Id*. at 272. Therefore, the Sixth Circuit held that plaintiff could not establish the packing caused "a significant number of reasonable consumers' confusion." *Id*.

Novo's misleading theory suffers from the same defects. Like the plaintiff in *Wysong*, Novo's pleaded facts are too threadbare to support the numerous inferences needed to establish its misleading theory. Novo has failed to plead any facts demonstrating what a reasonable consumer considers to be "personalized medications," "personalized semaglutide," or "personalized GLP-1s." Novo merely pleads its self-serving, narrow view of these terms. Missing entirely are alleged facts showing that reasonable consumers share Novo's narrow view, and have the same expectations as Novo. Further, Novo entirely fails to address how a reasonable consumer could plausibly be deceived by Amble's services, when Amble explains on its website the manner in which third-party doctors may prescribe medications, and Novo attached that very statement to its Complaint. Compl., Ex. B.

Instead, Novo conclusorily repeats, without referencing a single instance of actual confusion or supposed deception from a consumer, that Amble's advertising is likely to cause confusion or deception. Compl. ¶ 11 ("Defendant's marketing and other conduct is likely to confuse and deceive consumers into mistakenly believing that they are purchasing personalized weight-loss medicines, rather than drugs mass-produced in contravention of federal law."); ¶ 70 ("On information and belief, unless enjoined by this Court, Defendant's conduct will continue to confuse and deceive consumers."); ¶ 74 ("The above-described acts of Defendant have deceived and, if not enjoined, are likely to continue to deceive members of the general public."). Those 3 cites are Novo's sole allegations regarding consumer deception.

Novo's bare recital of this element of the cause of action is a "naked assertion [], devoid of further factual enhancement," and it cannot survive a motion to dismiss. *Iqbal*, 556 U.S. at 678.

Novo has failed to plausibly plead that Amble's advertisements and website mislead reasonable consumers, and thus, Novo's false advertising claims fail and should be dismissed.

c. Alternatively, Amble's "Personalization" Statements Are Non-Actionable Puffery

Alternatively, Amble's "Personalized GLP-1 Injections" statements are "opinion statements, not statements of facts" that are not actionable under the Lanham Act, and thus subject to dismissal. *See FedEx*, 97 F.4th at 453 ("Statements of opinion will not support a false-advertising claim. This includes puffery, which courts define as an "unverifiable exaggeration to prove a point"). In *FedEx*, the Sixth Circuit recently upheld the dismissal of false advertising allegations on the basis of puffery. The plaintiff brought Lanham Act claims against defendant's statements regarding the alleged "collapsing" of plaintiff's business model, the "soaring" default rate, and plaintiff's alleged "financial distress." *FedEx*, 97 F.4th at 456–57. The Sixth Circuit analyzed each of these statements and found them to be untestable or vague words, reasoning that there was no way to measure or reasonably interpret the statements as objective facts. *Id*.

Here, the same is true. There is no way for this Court to empirically test or measure what it means for a treatment plan or drug to be "personalized." *See FedEx*, 97 F.4th at 456–57. Therefore, the personalization statements are non-actionable puffery; as non-actionable puffery, they cannot be used to articulate a false statement required for a viable Lanham Act or ODTPA claim. As such, Novo's personalization theory fails to state a claim under the Lanham Act or ODTPA, and results in dismissal under 12(b)(6).

3. Novo Cannot Plead Facts to Establish Amble's Personalization Statements Are Material Because Doctors, Not Patients, Determine What to Prescribe.

Novo has also failed to plausibly plead facts to support the required element of materiality, *i.e.*, that the purportedly false advertisements were material and influenced consumers' purchasing decisions. *Ashley Furniture Indus. Inc. v. Am. Signature, Inc.*, No. 11-427, 2015 WL 12999664, *7

(S.D. Ohio, Mar. 12, 2015) (dismissing claim for failure to demonstrate materiality of the advertisements at issue). Once again, Novo merely recites the applicable legal standard and frames it as a fact. Compl. ¶ 64 ("Defendant's claims of personalization of its compounded semaglutide drugs are material to consumers."). This lone statement does not adequately plead materiality.

Moreover, Novo could never adequately plead materiality because doctors, not patients, determine whether and what medications are prescribed. *Geomatrix*, 82 F.4th at 484 (finding that "any deceptions on defendants' part was not the cause of consumers' decisions, for consumers were not the ones that decided to do anything"). Doctors, not patients, determine if a prescription medication is appropriate for treatment. Doctors, not patients, determine whether to prescribe FDA-approved medications or compounded medications. Thus, Amble's advertisements could never influence consumers' purchasing decisions because consumers only can purchase what doctors prescribe. Because Novo cannot establish that Amble's advertisements are material to consumer purchasing determinations, Novo's claims must be dismissed.

For each of the reasons outlined above, Novo's Lanham Act and ODTPA claims for false advertising under First and Second Causes of Action fail and should be dismissed.

B. Novo's ODTPA Claims Related to the Manner in Which Semaglutide API Is Created Are Preempted and Must be Dismissed.

In addition to the Lanham-mirroring ODTPA allegations in Count II, Novo also claims harm based statements on Amble's website on the quality, characteristics, and approval of the compounded medications that may be prescribed through Amble's telehealth platform, *i.e.*, the activity of compounding with semaglutide itself. Specifically, Novo alleges that:

> Defendant's acts in representing that its goods or services have sponsorship, ***approval***, ***characteristics***, ***ingredients***, uses, benefits, or quantities that they do not have or that Defendant has a sponsorship, approval, status, affiliation, or connection that it does not have are in violation of R.C. 4165.02(A)(7) and are likely to mislead consumers as to the ***standard, quality, or grade of Defendant's products*** in violation of R.C. 4165.02(A)(9).

Compl. ¶ 83. But Novo did not plead any allegations that Amble made statements relating to the "quality, standard, approval, characteristics, or grade" of compounded GLP-1s products. Indeed, Novo cites one of Amble's many disclaimers that compounded GLP-1s ***are not*** FDA-approved or FDA-reviewed for safety or effectiveness. Compl. ¶ 51. Thus, Novo's ODTPA claims cannot be based on alleged false or misleading statements, but must relate to the medications themselves.

And Novo's allegations related to the "standard, quality, or grade" of compounded semaglutide medications are impliedly preempted pursuant to 21 U.S.C. § 337(a). Federal law mandates that FDA—and FDA alone—has the authority to restrain and enforce the FDCA. 21 U.S.C. § 337(a) (prohibiting actions to enforce or restrain violations of the FDCA that are not brought in the name of the federal government); *see In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 935 (6th Cir. 2014) (affirming district court decision that plaintiff's state law claims were impliedly preempted because they were premised on defendants' violation of the FDCA). "A private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA — that is, when the state claim would not exist if the FDCA did not exist." *Reeves v. PharmaJet, Inc.*, 846 F. Supp. 2d 791, 797 (N.D. Ohio 2012). To avoid implied preemption, a claim must "'rely[] on traditional state tort law which had predated the federal enactments in question[].'" *Arnold v. CooperSurgical, Inc.*, 681 F. Supp. 3d 803, 826 (S.D. Ohio 2023) (quoting *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001)). "[T]he conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law—and that would give rise to liability under state law even if the FDCA had never been enacted." *Loreto v. Procter & Gamble Co.*, 515 F. App'x 576, 579 (6th Cir. 2013).

Here, despite its Complaint purportedly seeking to enforce state law, Novo really seeks to enforce the FDCA. Novo's entire ODTPA theory relies on requirements set forth in Section 503A

of the FDCA. Novo claims that the semaglutide used in compounded medications is "made with a 'semaglutide' manufactured via chemical synthesis." Compl. ¶ 38. Novo claims that this process is different from the process it uses "pursuant to its FDA approval . . . using recombinant DNA technology," and (according to Novo) results in higher impurity levels. Compl. ¶¶ 39-40. Novo seems to claim that these compounded medications fail to comply with Section 503A because the semaglutide used by compounding pharmacies is allegedly different than the semaglutide Novo uses in Ozempic® and Wegovy®. 21 U.S.C. § 353(a)(b)(A)(i)(III) (authorizing compounders to use API that is a component of an FDA-approved drug). Under Section 503A, compounders may use active pharmaceutical ingredients that are a "component of a drug" approved by FDA (like the semaglutide in Ozempic® and Wegovy®) to compound. 21 U.S.C. § 353(a)(b)(A)(i)(III). Only FDA—not Novo—gets to decide whether using chemical synthesis versus recombinant DNA technology results in any difference in the API such that the compounded medications are not made using a "component of a drug" approved by FDA as required by Section 503A. *See* 21 U.S.C. § 337(a) (reserving to FDA alone enforcement of the FDCA). FDA has made no such determinations.

Thus, Novo's claims seek to enforce its own interpretation of these federal requirements. There are no traditional state laws mandating the ingredients to use in compounded medications. Because there is no independent state law basis for Novo's claims, Novo—by definition—seeks to enforce the FDCA, which Novo knows full well it cannot do. As such, Novo's second cause of Action under the ODTPA claims is impliedly preempted.

VI. CONCLUSION

For the foregoing reasons, this Court should grant this Motion to Dismiss, and dismiss Plaintiff's Complaint with prejudice.

Respectfully submitted,

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CERTIFICATATION

Pursuant to Local Rule 7.1(f), the undersigned certifies that this case has not been assigned to a track yet and Defendant Amble Health, Inc. has filed an Unopposed Motion to Apply the Complex Track Page Limits Under L.R. 7(F) to All Briefing Relating to Defendant's Motion to Dismiss (ECF Doc. No. 19). The memorandum adheres to the page limitations for a complex case.

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CERTIFICATE OF SERVICE

This is to certify that on July 22, 2025, the foregoing *Motion to Dismiss for Failure to State a Claim* was electronically filed. Notice of this filing will be sent to all parties by operation of the United States District Court's CM/ECF electronic filing system. Parties may access this filing through the Court's system.

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